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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,359	09/23/2003	Masao Matsuoka	026350-090	9190
21839	7590	07/31/2006	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC				QIAN, CELINE X
POST OFFICE BOX 1404				ART UNIT
ALEXANDRIA, VA 22313-1404				PAPER NUMBER
				1636

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/667,359	MATSUOKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 June 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 21-26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 and 17-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 July 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0805</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

Claims 1-26 are pending in the application.

### ***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on 6/1/06 is acknowledged. The examiner inadvertently left out claim 20 from Group I. It will be examined with the elected claims. Accordingly, claims 9-16 and 21-26 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-8 and 17-20 are currently under examination.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Hino et al (Blood, 2002 November 16, Vol.100, No.11, pp. Abstract No.5522).

Hino et al. disclose a method to protect a transgene from silencing by introducing an insulator from sea urchin arylsulfatase, ARSI, into a lentiviral vector in both sense and antisense

orientation, and introduce the vector into HL-60 cells. Hino et al. disclose that said ARSI is able to prevent transgene from silencing in HL-60 myeloid progenitor cells (see abstract). Therefore, Hino et al. disclose the instantly claimed invention.

Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinmyo et al. (US 6,229,070).

Shinmyo et al. disclose a method for introducing a gene, wherein an insulator from sea urchin arylsulfatase, ARSI, is introduced concurrently with a transgene into plant cell, wherein the expression of the transgene is stabilized and more uniform than without the insulator (see Figure 1, and col. 4, lines 15-40, and Figure 7). Shinmyo et al. also disclose the insulator is introduced in an antisense orientation (col.6, 1<sup>st</sup> paragraph), which resulted in similar effect as the sense orientation. Therefore, Shinmyo et al. disclose the instantly claimed inventions.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 6, 7 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmyo et al.

The teaching of Shinmyo et al. is discussed above. However, Shinmyo et al. do not teach the claimed method wherein the transgene is introduced using a viral vector such as lentiviral vector.

It would have been obvious to one of ordinary skill in the art to use viral vector, such as lentiviral vector in the method of introducing transgene into a cell because lentiviral vectors are well studied in the art and used routinely in introducing transgenes into preferred cell type. The teaching of Shinmyo et al. demonstrate that ARI is able to ensure stable expression of transgene and prevent position effect which affects transgene expression, wherein such position effect occurs independent of the type of vector used to carry the transgene. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to use viral vectors, such as lentiviral vectors, instead of the plasmid vectors in delivering the transgene to a specific cell, wherein the ARI would protect the transgene from silencing. Therefore, the claimed invention would have been *prima facie* obvious at the time the invention was made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "wherein an insulator from sea urchin arylsulfatase gene is introduced concurrently with the transgene" renders the claims indefinite because it is unclear where the transgene and the insulator are introduced. Is it a cell, a plant, an animal or just a tube? Appropriate clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

